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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/482,682	01/14/2000	Daniel J. Von Seggem	5410-005-11	7337

7590 08/18/2005

Patent Group
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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/482,682

Applicant(s)

VON SEGGERN ET AL.

Examiner

Shanon Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,10,11,14-18,20-23,41,47,69 and 95-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-18,20-23,41,47,69 and 95-101 is/are allowed.
- 6) ☒ Claim(s) 1,4-8,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 96 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☒ Interview Summary (PTO-413) 7/5/5
Paper No(s)/Mail Date. 7/5/5
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2005 has been entered.

In the amendment to the claims submitted July 1, 2005, claims 1, 4-6, 10, 15, 16, 18, 20, 21, 41, 69, 95-101 are amended and claims 2, 3, 9, 12, 13, 19, 24-40, 42-46, 48-68, 70-94, 102 and 103 are cancelled. Claims 1, 4-8, 10, 11, 14-18, 20-23, 41, 47, 69 and 95-101 are pending and under consideration.

Double Patenting

Claim 96 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 95. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 95 is drawn to a method of producing an adenovirus by providing the packaging cell line according to claim 14 and producing an adenovirus particle. Claim 96 recites the same method steps using the same ingredients. However, claim 96 further states that the cell line of claim 14 complements a viral gene deficient in a vector genome. Since the cell line of claim 14 is required to comprise a sequence encoding an adenovirus structural protein (which would be

Art Unit: 1648

required to replicate a viral vector deficient in that structural gene by homologous recombination), it is determined that the characterization recited in claim 96 does not further recite a structural or functional limitation that is not already present in claim 95.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims 5 and 10 depend from claim 1, which requires a an isolated nucleic acid sequence comprising a TPL comprising (a) first and second different TPL exons from different adenoviruses, (b) an intron between exons of said TPL or (c) first, second or third same or different TPL exons, where at least 2 are from different adenoviruses. Claim 5 states that the TPL has SEQ ID NO: 32 and claim 10 is drawn to nucleic acid SEQ ID NOs: 43, 44, 47, 64 and 65. The specification teaches that SEQ ID NO: 32 comprises complete TPL exon 1, a native intron, TPL exon 2 and TPL exon 3, see paragraph 0158. SEQ ID NO: 32, as described, does not meet the criteria required by the TPL of claim 1 (a) or (c) because the exons of SEQ ID NO: 32 are not from different adenoviruses. SEQ ID NO: 32 also does not meet the criteria required by (b) of claim 1 because (b) requires an intro between the exons of the TPL and SEQ ID NO: 32 does not have an intron between exons 2 and 3. Therefore, there is a discrepancy between the requirements of claim 1 and the sequence of claim 5. Regarding claim 10, paragraph 0371 of the disclosure states that pDV67 and pDV69, corresponding to SEQ ID NO: 44 and SEQ ID NO: 47,

Art Unit: 1648

respectively, contain the complete Ad5 tripartite leader sequence. The complete Ad5 TPL sequence also does not meet the criteria required by claim 1 sections (a) - (c). There is no disclosure provided for what the individual components (exons and introns) are for the TPLs of pDV60 (SEQ ID NO: 43), pDV80 (SEQ ID NO: 64) or pDV90 (SEQ ID NO: 65), recited by claim 10. Therefore, it cannot be determined whether these sequences meet the requirements recited of the TPL in claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Logan et al. (PNAS. 1994; 81: 3655-3659, cited previously) as evidenced by Clark et al. (US 4,675,285).

Claims 1 and 11 are drawn to a vector comprising an isolated nucleic acid sequence encoding an adenovirus tripartite leader wherein the TPL comprises an intron between the exons of said TPL. Claim 4 states that the intron is native adenovirus intron 1.

Logan et al. teach plasmids pJAW 43 and “sub 360-L1,2,3”, which encode adenovirus type 2 tripartite leader sequences, see the first paragraph in the materials and methods section in column 1 on page 3655 and Figure 1. Although Logan et al. do not mention a native adenovirus intron between the TPL exons, Clark et al. discuss a second native intron within the Ad2 TPL sequence, see column 11, lines 59-64. It is evident from the discussion of Clark et al. that two

Art Unit: 1648

introns exist within the Ad2 TPL and Logan et al. teach three exons (L1,2,3) within the Ad2 TPL. Therefore, it is determined that the Ad2 TPL of pJAW 43 and "sub 360-L1,2,3" of Logan et al. contain a native intron between each of exons 1, 2 and 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan as evidenced by Clark et al. as applied to claims 1, 4 and 11 above, further in view of Curiel (US 5,871,727).

Claims 6-8 are drawn to an isolated nucleic acid comprising TPL exons 1-3, a promoter and a sequence encoding an Ad3 head domain and an Ad5 tail domain.

See the teachings of Logan et al. above. Logan et al. do not teach a sequence encoding an Ad3 head domain and an Ad5 tail domain.

Curiel teach a plasmid comprising a chimeric fiber gene encoding the tail of Ad5 and the head of Ad3, see Figure 13, column 16, line 64 to column 17, line 34 and column 24, lines 49-67.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the TPL sequences of Logan et al. with the chimeric adenovirus fiber gene of Curiel to enhance the translational efficiency of the heterologous chimeric fiber sequences of Curiel, see the abstract, Figure 3 and the discussion section of Logan et al. One of ordinary skill

Art Unit: 1648

in the art at the time the invention was made would also have been motivated to express the chimeric fiber gene of Curiel using the TPL sequences of Logan et al. to retarget recombinant adenoviruses, see the previous citations of Curiel. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of combining the TPL sequences of Logan et al. with the chimeric adenovirus fiber gene of Curiel because TPL sequences are present in native adenoviruses to express adenovirus genes and the chimeric fiber gene of Curiel is derived from adenoviruses. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Allowable Subject Matter

The prior art does not teach or suggest SEQ ID NOs: 32 or 26, as required by claim 14 or SEQ ID NO: 8 as required by claim 101. The prior art also does not teach or suggest SEQ ID NOs: 43, 44, 47, 64 or 65, as required by claim 18. Therefore, claims 14-18, 20-23, 41, 47, 69 and 95-101 are drawn to allowable subject matter. (Please note that claim 96 is objected above.)

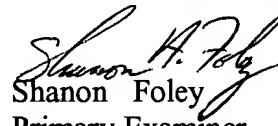
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
Art Unit 1648